

Food and Drug Administration, HHS

§ 520.2220d

beyond 5 days; withdraw 7 days before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 58 FR 6092, Jan. 26, 1993; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 8371, Feb. 25, 1997; 62 FR 23357, Apr. 30, 1997; 62 FR 35076, June 30, 1997; 62 FR 40932, July 31, 1997; 63 FR 59714, Nov. 5, 1998; 64 FR 18572, Apr. 15, 1999]

§ 520.2220b Sulfadimethoxine tablets and boluses.

(a) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter as follows:

(1) To 000069, approval for use as in paragraphs (d)(1), (d)(2), and (d)(3) of this section.

(2) To 000061, approval for use as in paragraph (d)(2).

(b) *Related tolerances.* See § 556.640 of this chapter.

(c) [Reserved]

(d) It is used as follows:

(1) *Cattle*—(i) *Amount.* 1.25 to 2.5 grams per 100 pounds body weight.

(ii) *Indications for use.* Treatment of foot rot, bacterial pneumonia, shipping fever, and calf diphtheria.

(iii) *Limitations.* Administer 2.5 grams per 100 pounds body weight for 1 day followed by 1.25 grams per 100 pounds body weight per day; treat from 4 to 5 days; do not administer within 7 days of slaughter; milk that has been taken from animals during treatment and 60 hours (5 milkings) after the latest treatment must not be used for food.

(2) *Dogs and cats.* (i) *Amount.* 12.5 to 25 milligrams per pound of body weight.

(ii) *Indications for use.* Treatment of sulfadimethoxine-susceptible bacterial infections.

(iii) *Limitations.* Administer 25 milligrams per pound of body weight on the first day followed by 12.5 milligrams per pound of body weight per day until the animal is free of symptoms for 48 hours. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Beef cattle and nonlactating dairy cattle*—(i) *Amount.* 12.5-gram-sustained-release bolus.

(ii) *Indications for use.* Treatment of shipping fever complex and bacterial pneumonia associated with organisms such as *Pasteurella spp.* sensitive to sulfadimethoxine; calf diphtheria and foot rot associated with *Sphaerophorus*

necrophorus sensitive to sulfadimethoxine.

(iii) *Limitations.* Administer one bolus for the nearest 200 pounds of body weight, i.e., 62.5 milligrams per pound of body weight. Do not repeat treatment for 7 days. Do not use in lactating dairy cattle. Do not administer within 12 days of slaughter. During treatment make certain that animals maintain adequate water intake. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 40 FR 43488, Sept. 22, 1975; 49 FR 36830, Sept. 20, 1984; 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997; 64 FR 15684, Apr. 1, 1999]

§ 520.2220c Sulfadimethoxine oral suspension.

(a) *Chemical name.* *N*-(2,6-Dimethoxy-4-pyrimidinyl) sulfanilamide.

(b) *Specifications.* Each milliliter of the drug contains 50 milligrams of sulfadimethoxine.

(c) *Sponsor.* See Nos. 000061 and 000069 in § 510.600(c) of this chapter.

(1) It is intended for use in the treatment of sulfonamide susceptible bacterial infections in dogs and cats and enteritis associated with coccidiosis in dogs.

(2) On the first day of treatment administer an oral dose of 25 milligrams per pound of body weight, then follow with a daily dosage of 12.5 milligrams per pound of body weight. Length of treatment will depend upon clinical response. Continue treatment until patient is asymptomatic for 48 hours. Maintain adequate water intake during the treatment period.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 59 FR 56000, Nov. 10, 1994; 61 FR 4875, Feb. 9, 1996; 62 FR 61625, Nov. 19, 1997]

§ 520.2220d Sulfadimethoxine-ormetoprim tablets.

(a) *Specifications.* Each tablet contains 120 milligrams (100 milligrams of sulfadimethoxine and 20 milligrams of ormetoprim), 240 milligrams (200 milligrams of sulfadimethoxine and 40 milligrams of ormetoprim), 600 milligrams (500 milligrams of sulfadimethoxine and 100 milligrams of ormetoprim), or